**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| EISAI R&D MANAGEMENT CO., LTD., EISAI INC., and EISAI CO., LTD.,<br><br>Plaintiffs,<br><br>v.<br><br>DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD,<br><br>Defendants. | **Civil Action No. 22-5950 (SRC)**<br><br>**OPINION** |

**CHESLER, U.S.D.J.**

This matter has come before the Court on the motion to dismiss all claims and counterclaims in this case for lack of subject matter jurisdiction, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(h)(3), by Plaintiffs Eisai R&D Management Co., Ltd., Eisai Inc., and Eisai Co., Ltd. (collectively, "Eisai.") Defendants Dr. Reddys Laboratories, Inc. and Dr. Reddys Laboratories, Ltd. (collectively, "DRL") have opposed the motion. On September 28, 2023, the Court held oral argument on the motion. For the reasons that follow, the motion will be granted.

This case arises out of a patent infringement dispute under the Hatch-Waxman Act between Eisai, which owns two patents covering its Halaven® pharmaceutical product, and DRL, which has filed ANDA No. 217473, seeking to make and sell a generic version of Halaven®. The following facts are undisputed. Halaven® (eribulin mesylate) is covered by two patents listed in the Orange Book, U.S. Patent No. 6,214,865 (the "'865 patent"), which expires on January 20, 2024, and U.S. Patent No. RE46,965 (the "'965 patent"), which expires in

2027. Non-party Sandoz filed an ANDA on December 20, 2019; Defendant DRL filed an ANDA in June of 2022. Both Sandoz and DRL filed paragraph III certifications for the '865 patent and paragraph IV certifications for the '965 patent. Neither generic company can enter the market until the expiration of the '865 patent in this coming January; the parties appear to have no dispute about the '865 patent, raise no arguments about it, and it plays no role in the discussion.

Eisai now moves to dismiss all claims and counterclaims in the case on the ground that this Court lacks subject matter jurisdiction. As to all claims in the Complaint, Eisai contends that the Court lacks subject matter jurisdiction because there is no justiciable case or controversy, on account of a covenant not to sue that Eisai has given to DRL. Eisai argues that the covenant divests this Court of subject matter jurisdiction over all claims in the Complaint because there is no longer any case or controversy over them. DRL's Answer asserts one counterclaim for declaratory judgment of non-infringement, unenforceability, and/or invalidity of the '965 patent. As to the counterclaim, Eisai also contends that the Court lacks subject matter jurisdiction because there is no justiciable case or controversy, but bases this not on the covenant but on challenges to the supporting factual allegations in the Answer, contending that they are speculative and insufficient to support independent subject matter jurisdiction.

The parties dispute who bears the burden of proof on this motion. Eisai contends that the proponent of jurisdiction bears the burden of establishing its existence, citing Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 104 (1998) ("the party invoking federal jurisdiction bears the burden of establishing its existence.") DRL argues that Plaintiff's motion should be understood as a motion to dismiss for mootness, and that, on such a motion, the movant bears a

heavy burden of proof. Plaintiff's reply brief does not respond to DRL's argument about mootness. So who is right?

In the context of this motion, both parties are right, in part, because the motion consists of two distinguishable parts: the motion to dismiss the Complaint, and the motion to dismiss the counterclaim. The Court agrees with DRL that the motion to dismiss the Complaint falls within the scope of the law of dismissal for mootness, and that the law places on Plaintiff the heavy burden, just as DRL contends, but that Eisai readily carries that burden. As will be explained further below, there is no genuine dispute between the parties about whether the revised covenant not to sue has mooted Plaintiff's claims in the Complaint: it has done so, and DRL all but admitted it at oral argument.

The law of mootness does not apply to Plaintiff's motion to dismiss the counterclaim, however: Eisai does not argue that the existence of the revised covenant has terminated the Court's subject matter jurisdiction over the counterclaim. Instead, Eisai moves to dismiss the counterclaim through a factual challenge under Rule 12(b)(1), and the ordinary legal standards to be applied to such challenges apply, including that the burden of proof of federal subject matter jurisdiction is borne by the proponent of jurisdiction, the counterclaim plaintiff.

## I. The motion to dismiss the Complaint

Shortly after DRL filed its ANDA application in 2022, Eisai filed the Complaint which initiated this action. The Complaint asserts one count of patent infringement of the '965 patent. Subsequently, Eisai delivered to DRL an executed covenant not to sue for infringement of the '965 patent. Eisai now moves to dismiss the Complaint, arguing that the Court lacks subject matter jurisdiction over the case because the covenant not to sue has eliminated any justiciable

case or controversy.

DRL's opposition complained that Eisai's tendered covenant not to sue was limited and conditional. Shortly before submitting its reply brief, Eisai issued a revised covenant not to sue which, it stated, made its promise not to sue for infringement of the '965 patent unconditional. At the hearing on this motion, the Court asked counsel for DRL whether there were any defects in the revised covenant not to sue, and counsel replied that there were none. DRL does not argue that any controversy remains over the single infringement claim in the Complaint.

Eisai contends that the motion to dismiss the Complaint, pursuant to Rule 12(b)(1), should be decided under the law of Rule 12(b)(1). DRL disagrees, arguing that "Eisai misstates the applicable burden of persuasion." (Def.'s Opp. Br. at 12.) DRL argues that the motion to dismiss the Complaint should be decided by applying the legal framework of mootness, which places upon the movant a "heavy burden of persuasion." The Court does not perceive this as a black-or-white choice: while the "voluntary cessation" mootness cases cited by DRL appear inapt,[1] ArcelorMittal is relevant but does less for DRL than Defendant suggests. ArcelorMittal did involve a plaintiff offering a covenant not to sue, a motion to dismiss declaratory judgment counterclaims for lack of subject matter jurisdiction, and a mootness argument. ArcelorMittal v. AK Steel Corp., 856 F.3d 1365, 1367-1369 (Fed. Cir. 2017). The Federal Circuit held that the

[1] For example, DRL cites Friends of the Earth for the proposition that, "ordinarily, voluntary cessation does not suffice to moot a case." (Def.'s Opp. Br. at 12.) What the Supreme Court actually wrote is: "A defendant's voluntary cessation of allegedly unlawful conduct ordinarily does not suffice to moot a case." Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 174 (2000). The present circumstances do not involve a defendant's voluntary cessation of allegedly unlawful conduct; they are entirely different. The "voluntary cessation" of the defendant in the cases cited by DRL had nothing to do with a plaintiff's voluntary cessation of litigation.

plaintiff bore a heavy burden:

> [T]he patentee "bears the formidable burden of showing" "that it 'could not reasonably be expected' to resume its enforcement efforts against" the covenanted, accused infringer. In this context, that requires ArcelorMittal to show that it actually granted a covenant not to sue to Defendants, and that the covenant enforceably extinguished any real controversy between the parties related to infringement of the RE'153 patent.

Id. at 1370 (citations omitted). In the instant case, Eisai appears to have carried the formidable burden of showing that it cannot be reasonably expected to resume its enforcement efforts against the accused infringer: at the hearing, when questioned about remaining defects in the revised covenant, DRL did not assert that the covenant failed to fully protect DRL against future litigation, but instead said there were no defects. There is no dispute that the revised covenant enforceably extinguished any real controversy between the parties related to infringement of the '965 patent. Eisai has met its heavy burden under ArcelorMittal.

The Court finds that there is no longer any justiciable case or controversy related to the single claim in the Complaint for infringement of the '965 patent. The revised covenant not to sue has extinguished the controversy. DRL has raised some challenges about the procedural propriety of Eisai's motion to dismiss its own complaint. The Court need not reach these questions because, as Wright and Miller states: "No formal motion need be made to raise the subject matter jurisdiction issue." § 1393 Waiver of Certain Defenses—Rule 12(h)(3), 5C Fed. Prac. & Proc. Civ. § 1393 (3d ed.) It is clear that, regardless of the naming or framing of the application challenging subject matter jurisdiction, the issue may be raised by any party at any point in a litigation. Moreover, this Court has the independent obligation to consider the issue at all points and the authority to dismiss a complaint over which it lacks subject matter jurisdiction:

> Moreover, courts, including this Court, have an independent obligation to

> determine whether subject-matter jurisdiction exists, even in the absence of a challenge from any party. . . . [W]hen a federal court concludes that it lacks subject-matter jurisdiction, the court must dismiss the complaint in its entirety.

Arbaugh v. Y & H Corp., 546 U.S. 500, 514 (2006); Federal Rule of Civil Procedure 12(h)(3).

Having found that there is no longer a justiciable case or controversy over the Complaint, the Court will dismiss it for lack of subject matter jurisdiction. The remining question is: does this Court have independent declaratory judgment jurisdiction over the counterclaim?

**II. The motion to dismiss the counterclaim**

The parties, for the most part, agree that the motion to dismiss the counterclaim turns on the issue of the case-or-controversy requirement established by Article III of the Constitution. DRL cites the Federal Circuit's decision in ArcelorMittal, which looks to the Supreme Court's MedImmune decision for the legal standard to apply to such questions:

> *Aetna* and the cases following it do not draw the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not. Our decisions have required that the dispute be "definite and concrete, touching the legal relations of parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." In *Maryland Casualty Co. v. Pacific Coal & Oil Co*., 312 U.S. 270, 273 (1941), we summarized as follows: "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (citations omitted.) In overview, the ArcelorMittal Court stated: "there is no bright-line rule for determining whether an action satisfies the case or controversy requirement." ArcelorMittal, 856 F.3d at 1370. Instead, all the circumstances must be considered. Id.

Eisai moves to dismiss the counterclaim for lack of subject matter jurisdiction, pursuant

to Rule 12(b)(1). The Third Circuit has summarized the fundamental principles of Rule 12(b)(1) challenges as follows:

> A facial 12(b)(1) challenge, which attacks the complaint on its face without contesting its alleged facts, is like a 12(b)(6) motion in requiring the court to "consider the allegations of the complaint as true." *Petruska v. Gannon Univ.*, 462 F.3d 294, 302 n.3 (3d Cir. 2006) (internal quotation marks omitted). But a factual 12(b)(1) challenge attacks allegations underlying the assertion of jurisdiction in the complaint, and it allows the defendant to present competing facts. *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 358 (3d Cir. 2014). When considering a factual challenge, "the plaintiff [has] the burden of proof that jurisdiction does in fact exist," the court "is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case," and "no presumptive truthfulness attaches to [the] plaintiff's allegations … ." *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). And, when reviewing a factual challenge, "a court may weigh and consider evidence outside the pleadings." *Constitution Party of Pa.*, 757 F.3d at 358 (internal quotation marks omitted).

Hartig Drug Co. v. Senju Pharm. Co., 836 F.3d 261, 268 (3d Cir. 2016).

As already discussed, the parties disagreed about which side bears the burden of proof that subject matter jurisdiction exists, and this Court has determined that, as the motion to dismiss the counterclaim is not based on mootness, DRL bears that burden. Aside from the question of which party bears what burden of proof, DRL does not dispute that the customary Third Circuit principles regarding facial and factual challenges to subject matter jurisdiction apply here. In fact, DRL agrees that "[c]lassifying an attack as facial or factual sets the standard of review." (Def.'s Opp. Br. 27.) The Court will apply the law of motions to dismiss, pursuant to Rule 12(b)(1), as summarized in the quote above from Hartig.

Plaintiff's motion to dismiss the counterclaims relies on facts and evidence from outside the Answer. DRL, nonetheless, argues that Plaintiff's challenge "is really a ***facial*** attack disguised as a factual attack." (Def.'s Opp. Br. at 27.) DRL attempts to persuade that the Third

Circuit has a bright-line rule that precludes a pre-answer attack.[2] As Eisai demonstrates in reply, there is no such bright-line rule: any Rule 12(b)(1) motion may be facial or factual. Here, it is factual.

The Court agrees with DRL that, setting aside the question of the persuasive burden, the issue here is whether "DRL's declaratory judgment counterclaims adequately alleged a judicially cognizable injury-in-fact." (Def.'s Opp. Br. at 13.) Eisai has raised a factual challenge pursuant to Rule 12(b)(1), and the counterclaim plaintiff, DRL, bears the burden of proof that jurisdiction does, in fact, exist.

DRL's Answer pleads the following allegations relevant to the issue at bar:

> 23. DRL is blocked from receiving final approval and prevented from actually entering the market because the First ANDA Applicant may have 180-day generic market exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv).[3]
>
> 25. The First ANDA Applicant may forfeit its 180-day market exclusivity if another ANDA holder (such as DRL) secures a final court decision, from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the '965 patent is found invalid, unenforceable, and/or not infringed.
>
> 26. On information and belief, delaying judicial consideration of DRL's Counterclaims could result in depriving DRL of the ability to trigger the First ANDA Applicants potential 180-day market exclusivity pursuant to 21 U.S.C. § 355(j)(5)(D), thus blocking DRL from receiving final approval and prevent DRL from actually entering the market.
>
> 28. The dispute as to noninfringement, unenforceability, and/or invalidity of the '965 patent presents a justiciable Article III controversy where a judgment in favor of DRL may trigger the First ANDA Applicant's potential 180-day period of generic marketing exclusivity.

---

[2] Because Eisai moved to dismiss the counterclaim in lieu of answering it, it could be considered a pre-answer attack.

[3] For convenience, this Opinion will use the term "exclusivity" to refer to 180-day generic market exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv).

In short, Eisai argues that the allegations that Sandoz "***may***" have market exclusivity (¶ 23) and that a judgment in favor of DRL "***may***" trigger such exclusivity (¶ 28) are too speculative to provide a basis for subject matter jurisdiction. Eisai contends that: 1) "[p]ublic records indicate that Sandoz has already forfeited its 180-day exclusivity" (Pl.'s Br. at 12); and 2) even if Sandoz has not forfeited exclusivity, the Sandoz exclusivity period would not actually delay DRL's market entry.

*A. Has Sandoz forfeited its exclusivity?*

This issue is at the heart of Eisai's challenge, and also at the heart of DRL's theory of the controversy on which subject matter jurisdiction is predicated.[4] First, Eisai cites the relevant forfeiture provision of the Hatch-Waxman Act:

> (D) Forfeiture of 180-day exclusivity period.
>
> (i) Definition of forfeiture event. In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:
>
> . . .
>
> (IV) Failure to obtain tentative approval. The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

21 U.S.C. § 355(j)(5)(D). Then, Eisai notes that the 30-month period lapsed in June of 2022, 30 months after Sandoz filed its ANDA. Next, Eisai states that public records reflect that Sandoz

[4] Paragraph 28 in the Answer states that there is a justiciable controversy here because a judgment in favor of DRL may trigger the first filer's market exclusivity period. Eisai argues, in short, that the market exclusivity period has already been forfeited and therefore cannot be triggered by a favorable judgment.

has not obtained tentative approval. Eisai also argues that there is no evidence that Sandoz' failure to obtain tentative approval falls within the available statutory exception, "unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed." In conclusion, Eisai argues that Defendant cannot show that Sandoz will hold a future market exclusivity, or that DRL has suffered a concrete and actual injury redressable by a judgment in its favor.

In opposition, DRL first argues that the Court should limit itself to the facts alleged in the Answer, an argument that this Court has already rejected, and that DRL itself undermined by offering evidence of the FDA's Paragraph IV list,[5] contending that the status of Sandoz's exclusivity period "is set forth" in this list. (Def.'s Opp. Br. at 7.) Next, DRL responds to Eisai's factual challenge regarding the Sandoz exclusivity period, relying on its evidence of the Paragraph IV list. In short, DRL contends that there is a blank space in a certain spot on that list, which means that the FDA has not yet made a determination about the Sandoz exclusivity. This Court takes judicial notice that, on the most recently posted version of the FDA Paragraph IV Patent Certifications list, dated October 16, 2023, the "180-day status" field for eribulin mesylate is still blank.[6] The Court agrees that, based on the guidance provided by the FDA on its website,[7] the blank field means that the FDA has not yet made a determination about the Sandoz exclusivity. The Court further notes that the FDA website states:[8]

---

[5] Defendant's Nero Dec. Ex. 3 states that it is that list as of May 2, 2023.
[6] https://www.fda.gov/media/166048/download?attachment (last accessed November 2, 2023.)
[7] As to the contents of this field, the FDA website states: "If FDA has not made any of the above determinations, this column will be blank." (https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions, last accessed November 2, 2023.)
[8] https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions (last accessed November 2, 2023.)

> For certain 180-day exclusivity decisions that require analysis by FDA, including those under the failure-to-obtain-TA in 30 months and failure-to-market provisions, it is FDA's practice to make these decisions in the context of specific ANDAs that are otherwise eligible for approval (i.e., when a first applicant's ANDA or a subsequent applicant's ANDA is ready for approval). Many factors may influence eligibility for exclusivity up to the time an application is ready for approval (e.g., patent expiration, failure to obtain a tentative or final approval within 30 months, withdrawal of ANDA) and thus could render a premature eligibility determination incorrect.

The available evidence supports the inference that, because no ANDA has yet become eligible for approval, the FDA has not yet made a determination about the Sandoz market exclusivity.

As to the question of whether Sandoz has forfeited its market exclusivity, the Court is left to consider three things: 1) the language of the statutory forfeiture provision; 2) the evidence that the FDA has not yet made a forfeiture determination; and 3) the absence of any other evidence relevant to the Sandoz forfeiture question. It is at this point that the issue of which party bears the burden of proof becomes crucial. Because this Court has concluded that, under Third Circuit law, DRL, the counterclaim plaintiff, "will have the burden of proof that jurisdiction does in fact exist," Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977), the Court finds that DRL has failed to prove that Sandoz retains its potential market exclusivity. There is no dispute that 21 U.S.C. § 355(j)(5)(D)(i)(IV) provides that a first applicant that fails to obtain tentative approval within 30 months of application forfeits its right to market exclusivity unless certain conditions of exception are met. There is no dispute that more than 30 months have elapsed since the date on which Sandoz filed its ANDA. DRL has offered no evidence in support of the inference that the first ANDA filer has met any condition of exception to the statutory provision. The evidence of record supports the inference that the FDA has not yet made any determination about Sandoz and market exclusivity, and there is no basis to use this

fact to view an eventual determination of forfeiture as more probable or less probable. The evidence of record supports the inference that Sandoz has forfeited its potential market exclusivity. DRL has failed to prove that Sandoz has retained its potential market exclusivity. DRL's theory of independent subject matter jurisdiction is premised on the assertion of a regulatory injury-in-fact, due to the eligibility of Sandoz for market exclusivity. If Sandoz has not retained its potential market exclusivity, then a judgment in Defendant's favor cannot trigger that market exclusivity, as pled in paragraph 28 of the counterclaim. DRL has failed to carry its burden of proof of its theory of independent subject matter jurisdiction.

Eisai contends that the Medeva case, which received a non-precedential affirmance without opinion from the Federal Circuit, demonstrates similar reasoning. In Medeva, the plaintiff asserted a factual attack, pursuant to Rule 12(b)(1), on a counterclaim premised on redress of a regulatory injury to a second ANDA filer due to the market exclusivity period of the first ANDA filer. Medeva Pharma Suisse A.G. v. Par Pharm., LLC, 774 F. Supp. 2d 691, 693-96 (D.N.J. 2011), *aff'd*, 461 F. App'x. 933 (Fed. Cir. 2012). The Medeva plaintiff argued that the defendant lacked the injury-in-fact needed to support declaratory judgment jurisdiction over a counterclaim under the Patent Act. Id. at 694. The Medeva Court concluded that, based on the fact that more than 30 months had elapsed since the first ANDA was filed, and the fact that the first filer had not yet obtained tentative approval, the first filer had forfeited market exclusivity, which eliminated the injury-in-fact on which jurisdiction was premised. Id. at 698.

DRL attempts to distinguish Medeva but fails to do so persuasively. DRL contends that, when Medeva was decided in 2011, the FDA did not publicly disclose the FDA Paragraph IV Patent Certifications list, as it does today. Yes, the publication of the FDA Paragraph IV Patent

Certifications list provides solid evidence that, as of October 16, 2023, the FDA had not made a determination about the market exclusivity of the first filer for Halaven®. DRL does not, however, explain how the availability of this evidence helps its case or makes a difference; as the Court has already stated, this evidence that the FDA has not yet made a determination does not make an ultimate determination of forfeiture any more or any less probable. DRL's arguments attempting to distinguish Medeva simply rehash the debate over who bears the burden of proof here. DRL argues:

> Eisai, DRL, and the Court would not be aware of any changes in, or reviews of, the requirements for FDA approval that could justify taking the 30-month tentative approval deadline off of the table. In the absence of such vital information, this Court cannot conclude as a factual matter that Sandoz has forfeited its 180-day exclusivity for failure to obtain tentative approval.

(Def.'s Opp. Br. at 23.) DRL's contention that the Court ***cannot*** make a factual determination on this motion is contrary to Third Circuit law:

> At the outset we must emphasize a crucial distinction, often overlooked, between 12(b)(1) motions that attack the complaint on its face and 12(b)(1) motions that attack the existence of subject matter jurisdiction in fact, quite apart from any pleadings. The facial attack does offer similar safeguards to the plaintiff: the court must consider the allegations of the complaint as true. The factual attack, however, differs greatly for here the trial court may proceed as it never could under 12(b)(6) or Fed. R. Civ. P. 56. Because at issue in a factual 12(b)(1) motion is the trial court's jurisdiction - its very power to hear the case - there is substantial authority that the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case. In short, no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. Moreover, the plaintiff will have the burden of proof that jurisdiction does in fact exist.

Mortensen, 549 F.2d at 891. This Court is authorized to make such factual determinations as are supported by the evidence the parties present to it, and the counterclaim plaintiff bears the burden of proof here. DRL's position is tantamount to arguing that, because it cannot obtain the

evidence it needs to show that the first filer is entitled to a statutory exception to the forfeiture provision, DRL should be credited with having proven it. It doesn't work that way under the applicable Third Circuit law.

Similarly, in DRL's sur-reply brief, DRL argues that Eisai's arguments about DRL's regulatory status are speculative. But, in the end, since the available evidence shows that the FDA has not yet determined market exclusivity for any ANDA application related to Halaven®, both parties are left to speculate about what might happen down the road. The only hard fact here is that over 30 months have passed since the first filer's application. The parties do not dispute that the first filer has not received tentative approval. Thus, as already explained, the Court's decision on subject matter jurisdiction over the counterclaim turns on the question of who bears the burden of proof. This Court has determined that DRL, the proponent of independent declaratory judgment jurisdiction over the counterclaim, bears the burden of proof, and that it has offered only speculation about how the first filer might end up, in a reversal of fortune, with its market exclusivity preserved and available to delay DRL's potential market entry. The Court agrees with Plaintiff that, as in Medeva, "any potential barrier that could result from a subsequent approval and reinstatement of [the first filer's] market exclusivity is speculative at best, and does not meet the Article III requirement of actual or imminent injury for standing." Medeva, 774 F. Supp. 2d at 698.

This Court returns to the formulation of the case-or-controversy requirement set forth by the Supreme Court in Medimmune:

> [T[he question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

MedImmune, 549 U.S. at 127. As to the counterclaim, DRL has failed to show that there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The motion to dismiss the counterclaim will be granted, and the counterclaim will be dismissed for lack of subject matter jurisdiction.[9]

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J

Dated: November 7, 2023

[9] Because the Court finds that Eisai's first argument for dismissal of the counterclaim has succeeded, it need not reach its argument in the alternative that DRL has failed to show that the first filer's market exclusivity would delay market entry of DRL's generic product.